POLICY AND PROCEDURES

OFFICE OF THE CENTER DIRECTOR

Continuity of Operations (COOP)

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PURPOSE

The purpose of this MAPP is to describe CDER's Continuity of Operations Program (COOP), the responsibilities of COOP Members and the procedures to be followed to assure CDER is compliant with governing laws, regulations and policies. This will ensure CDER can continue essential functions during a wide range of emergencies. Specific program elements can be found in office COOP plans which are available on the CDER COOP Website.

BACKGROUND

Presidential Decision Directive 67 (PDD 67) issued 21 October 1998, requires all federal agencies to develop Continuity of Operations Plans for essential operations and the subsequent FEMA Federal Preparedness Circular 65 (FPC 65) and Federal Continuity Directive 1 (FCD-1): details the mandatory requirements for Federal COOP Plans. The CDER Office of the Center Director's Counterterrorism and Emergency Coordination Staff (CTECS) is tasked with the development and ongoing maintenance of CDER's Continuity of Operations Program.

POLICY

It is CDER policy that mission-essential functions shall continue effectively and without interruptions, by implementing and maintaining an effective and viable Continuity of Operations Program.

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RESPONSIBILITIES

The Center Director

- Oversees and supports the Program and the Senior Leadership COOP Plan, including the sequencing of events during an activation, and ensures appropriate notification procedures are followed.
- Approves lines of succession and delegations of authorities to be included in the CDER Senior Leadership plan.
- Issues an annual statement of endorsement.
- Ensures that the CDER staff is aware of responsibilities and procedures to be followed during COOP exercises and events.
- Participates in Training, Testing and Exercises.
- Appoints CDER COOP Coordinator

Office Directors

- Designate a Primary and Alternate COOP Coordinator and COOP Emergency Relocation Group (CERG) members.
- Work with the office COOP coordinator to develop, maintain and revise the office COOP Plan, annually or as required.
- Determine organization's essential functions, which must continue during a COOP emergency.
- Provide lines of succession and delegations of authority to be included in the Office COOP Plan.
- Review the Office COOP Plan at least annually and sign the plan as required.
- Participate in training, testing, and exercises.

The CDER COOP Coordinator:

- Advises CDER leadership of significant issues related to the COOP Program.
- Coordinates all aspects of CDER's Program with the Agency and other external stakeholders.
- Provides guidance and oversees activities for all COOP Office Coordinators.
- Maintains an inventory of laptops and other equipment that can be deployed during a COOP event.
- Provides annual and quarterly activity reports to the Agency as required.
- Provides training to Coordinators on a periodic basis.
- On an annual basis, collects updated Office COOP plans signed by Office. Directors and validates to the Agency that COOP requirements have been met.
- Maintains an inventory of emergency relocation sites in FDA buildings.
- Posts updated office COOP plans to the CDER intranet webpage.
- Continually searches for ways to improve the COOP program.
- Maintains the COOP site on Inside.FDA.

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The Office COOP Coordinator

- Secures and maintains an approved telework agreement as described in FDA Standard Operating Procedure (SOP) 600-04 "FDA Telework Policy."
- In concert with the Office Director, reviews the Office COOP Plan annually to insure that it is up-to-date and adhered to.
- Activates the Office plan during exercise or actual COOP events. At the direction
 of the Office Director, coordinates notifications and relocations of CERG
 members.
- Maintains proficiency in the use of the Emergency Notification System (ENS), including database management, use of various features, adding and deleting personnel, and other functions.
- Ensures CERG members receive required training.
- Instructs CERG members on the use of the ENS and the importance of accurate contact information.
- Validates home use COOP laptops are logged into the network a minimum of once a month.
- Conducts all required quarterly and annual exercises.
- Maintains familiarity with the SOP on COOP Coordinators located on Inside.FDA.

COOP Emergency Relocation Group (CERG) Member:

- Is familiar with the office COOP Plan, Coordinator, and other CERG members
- Participates in quarterly call-downs and annual relocation exercises.
- Is prepared to be fully functional and capable of performing essential functions while working from home or from an alternate relocation site, during an exercise or actual emergency event (for up to 30 days).
- Ensures personal contact information in the emergency notification system is current.
- Knows the assembly location in the event of a building evacuation during duty hours
- Knows the CDER Emergency Relocation Sites (ERS) locations and how to get to them from the workplace and residence.
- Ensures availability of necessary resources (contact information, call-in numbers, equipment, data bases, etc.).
- Identifies an alternate when not available.
- Identifies and prepares vital records for use during COOP activation.

PROCEDURES

- Office Director identifies a COOP Coordinator to manage the Office program.
- The Office COOP Coordinator contacts the CDER COOP Coordinator for instruction and guidance.

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- Office Director and Office COOP Coordinator, utilizing a customized CDER COOP plan template, develop a plan specific to the office to:
 - 1. Identify essential staff (aka CERG Members) who must be available during emergencies.
 - 2. Identify essential functions of the office.
 - 3. Designate orders of succession and delegations of authority.
 - 4. Identify continuity facilities or home work locations and providing instructions for staff.
 - 5. Identify continuity communications (Emergency Notification System) procedures.
 - 6. Adhere to Tests, Training, and Exercises (TT&E) requirements.
 - 7. Describe devolution of control and direction.
- Office COOP Coordinator works with CDER COOP Coordinator to:
 - 1. Finalize and implement the office plan.
 - 2. Update the office plan annually or as needed.
 - 3. Learn the automated ENS and populate the database.
 - 4. Provide training to office CERG members.
 - 5. Conduct quarterly call-down and annual relocation exercises.
 - 6. Prepare quarterly and annual reports.

REFERENCES

- 1. Presidential Decision Directive 67 (PDD 67) issued 21 October 1998: http://www.fas.org/irp/offdocs/pdd/pdd-67.htm
- 2. FEMA Federal Preparedness Circular 65 (FPC 65): http://www.fema.gov/pdf/library/fpc65 0604.pdf
- 3. Federal Continuity Directive 1 (FCD-1): http://www.fema.gov/library/viewRecord.do?id=6888
- 4. SOP for Office COOP Coordinators located in Inside.FDA, the FDA Intranet site

DEFINITIONS

COOP Emergency: a condition which requires the relocation of CDER personnel from their normal work location to an emergency relocation site (ERS); specifically, employees would work from home or from a previously identified location.

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MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 4800.2

Disaster Levels: The COOP Plan responds to four levels of disasters that may disrupt normal business activities:

Level 4: Part of CDER White Oak (WO) building or other occupied space housing is affected.

Level 3: Entire CDER WO building or other occupied space is closed or affected.

Level 2: The White Oak Campus and surrounding area affected.

Level 1: Washington, D.C. Metropolitan Area affected.

Emergency Notification System: For each CDER office, a list of the specific individuals who need to be notified of an emergency and how such notification will be made. Most offices employ a call-down system.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

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